DEP ISSUE PROFILE

Biomedical Waste Management Rules

revised: July, 1995 **contact:** (207) 287-2651

Background

The Biomedical Waste Management Rules became effective on January 1, 1991. The rules were developed and implemented as a result of legislation responding to public concerns about the potential public health and environmental hazards posed by medical waste.

The rules identify biomedical waste subject to regulation; require the registration of biomedical waste generators; and establish minimum standards for packaging, labeling, handling, storage, transportation, treatment and disposal of biomedical waste requirements. The rules also specify facility siting, operating and reporting requirements and establishes a biomedical waste tracking or manifest system.

What is biomedical waste?

The rules describe **seven categories** of biomedical waste.

1. Discarded human blood, blood products, and body fluids which are removed during surgery, autopsy, obstetrics, emergency care or embalming.

2. Waste saturated with human blood, blood products, or body fluids. The intent of this category is to include waste generally associated with an acute care facility. It is not intended for small bandages and gauzes generated at doctors' or dentists' offices.

3. Human pathological waste including tissues, organs and anatomical parts discarded from surgery, autopsy, obstetrics and laboratory procedures.

4. Discarded sharps used in patient, animal or cadaver care or in medical and biomedical research laboratories.

5. Discarded cultures and stocks of infectious agents and the culture dishes and devices used to transfer, inoculate and mix cultures; discarded clinical specimens and the associated containers or vials; discarded biologicals; and waste from the production of biologicals and recombinant DNA research.

6. Discarded carcasses, body parts, bedding and other waste generated by research facilities from animals containing organisms or agents not usual to the normal animal environment and which are pathogenic or hazardous to humans. This category does not include animal carcasses which have died of natural causes or been euthanized.

7. The following wastes may also be managed as biomedical waste.

   A. Cytotoxic (Antineoplastic) drugs not identified as hazardous wastes in Chapter 850 of e Department of Environmental Protection regulations. Several chemotherapy drugs are listed as hazardous waste. Contact the Department for more information.

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B. Chemotherapy waste - Consisting of all materials that have come in contact with, and have no more than trace amounts of, cytotoxic (Antineoplastic) agents.

What is *not* biomedical waste?

- Human remains;
- Urine and feces;
- Sludge, septage and wastewater; and
- Bandages which are only spotted with blood.

What is required of biomedical waste generators?

- Registration of each biomedical waste generating facility. A facility identification number will be issued by the Department upon registration. This number must appear on all containers of biomedical waste transported off-site.

- Determination of amount of biomedical waste generated per month. If the total amount generated is *less than 50 pounds* then the following provisions apply:

  1. The generator need *only* manage **categories 4 and 5** described above.

  2. The generator is not required to prepare a written biomedical waste management plan.

  3. The generator may transport its waste to another generator, a transfer facility, or a treatment facility without preparing a manifest.

  Generators of *more than 50 pounds* per month must manage all seven categories of biomedical waste, develop a management plan and utilize a licensed biomedical waste transporter for all off-site shipments of biomedical waste.

  Recent legislative changes now allow generators to mail properly packaged sharps to a licensed treatment facility. The U.S. Postal Service enforces strict packaging guidelines. Several companies market containers that meet all applicable standards and include shipping and disposal costs in the purchase price. Contact the DEP for more information.

How must biomedical waste be packaged, labeled and stored?

Biomedical waste other than sharps and bulk liquids must be packaged in sealed red bags which are leak proof and rip resistant. Sharps shall be placed in rigid leak and puncture resistant containers. Bulk liquids to be transported off-site shall be packaged in unbreakable flasks or bottles. All biomedical waste to be transported off-site shall, in addition to the above requirements, be placed in rigid containers. These outer containers shall be labeled immediately after packaging with the name, address, telephone number and generator's registration number.

All biomedical waste must be stored in a secure area designated for this material. Pathological waste, cultures, and animal carcasses stored anywhere for more than 24 hours must be refrigerated.

What is required of licensed biomedical waste transporters?

Any person transporting biomedical waste must obtain a license from the Department *unless* the person is the generator and waste is transported to another medical facility or to a licensed biomedical waste transfer, treatment or disposal facility *and* the amount transported is less than 50 pounds. The license must cover each business location, conveyance, and operator.

All transporters of biomedical waste are required to have the necessary equipment and training to deal with any biomedical spills.

Generators of biomedical waste who employ a licensed transporter must initiate a four part manifest. Copy four of the manifest is retained by the generator, copy three is retained by the transporter, copy two is retained by the treatment, storage or disposal facility and copy one is returned to the generator by the biomedical treatment facility. If the generator does not receive copy one within 35 days of shipment, the Department must be notified. All records are required to be retained for three years, unless enforcement action is pending in which case the retention time is automatically extended until the action is resolved.

How is biomedical waste treated?

Most biomedical waste generated in Maine must be incinerated. The exceptions to this are that pathological waste may be interred and discarded blood and body fluids may be discharged through a sewer to a publicly owned wastewater treatment works or properly functioning septic system.

What is a biomedical waste transfer facility?

Anyone operating a biomedical waste transfer facility must obtain a license from the Department.

A biomedical waste transfer facility is a transportation related facility where biomedical waste is held during the normal course of transportation. It includes loading docks, parking areas, and storage areas. The transfer of biomedical waste from one licensed transporting conveyance to another is an example of an activity restricted to a transfer facility.

Biomedical waste may not be stored for more than 96 hours at a licensed transfer facility.

What is a biomedical waste treatment facility?

A biomedical waste treatment facility is a facility where biomedical waste is rendered non-infectious and unrecognizable. In Maine, biomedical waste treatment consists of incineration.

Any facility wishing to incinerate biomedical waste must obtain two licenses from the Department. One is a biomedical waste treatment facility license obtained from the Bureau of Hazardous Materials and Solid Waste Control and the second is an air emission license obtained from the Bureau of Air Quality Control.

All treatment facilities are subject to design and performance standards to insure adequate treatment. All incinerators must meet a minimum temperature of 1800°F in the secondary chamber with a minimum retention time of 1.0 second. Incinerators burning chemotherapy waste must maintain a temperature of 2000°F with a retention of time of 2.0 seconds. Any incinerator which cannot meet these standards must be upgraded or replaced to continue treating biomedical waste. (Please refer to Chapter 900 of the Department's rules for a description of other performance standards.)

Once burning is completed, the residual incinerator ash must be analyzed for hazardous components prior to landfilling. Incinerator ash is considered to be, at a minimum, a special waste.

Where can I get more information?

For more information on the Biomedical Waste Management Rules, or for the answers to

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Department of Environmental Protection
Bureau of Hazardous Materials and Solid Waste Control
Division of Oil & Hazardous Waste Facilities Regulation
State House Station #17
Augusta, Maine 04333-0017
Telephone (207) 287-2651
Attn: Biomedical Waste Program